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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
CELGA, B

ART UNIT
1811

PAPER NUMBER

DATE MAILED: 01/13/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File
copy

Office Action Summary

Application No.

08/796,164

Applicant(s)

Stamler et al.

Examiner

Bennett Celsa

Group Art Unit

1811



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-62 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-62 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-62 are currently pending.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3 and 7-9, drawn to methods of using a nitrosating agent for methods affecting NO or O₂ metabolism and the treatment of disease classified in class 514, subclasses 19, 550 etc depending upon the nitrosating agent..
 - II. Claims 4 and 23, drawn to a method for preserving organs using S-nitrosated hemoglobin, classified in class 435, subclass 1.1+.
 - III. Claims 5-6, drawn to a method of treating a blood borne disease, such as malaria, by use of nitosothiol and blood replacement therapy, classified in class 524, subclass 532+ and Class 604, subclass 4+.
 - IV. Claims 10-22, and 24-32 and 40-46 drawn to deoxy/oxy nitrosylated hemoglobin and SNO-Hb[FeII]O₂ or SNO-Hb[FeII] preparation and a method of making and use thereof, classified in class 514, subclass 6+.
 - V. Claims 33-34 drawn the use of a substance to regulate platelet activation, classified in Class 514, subclass 822
 - VI. Claims 35-39, drawn to a composition comprising polynitrosated hemoglobin and method of making thereof, classified in class 514, subclass 6+.

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VII. Claims 47-49 drawn to a NO donor (e.g. diazeniumdiolates, nitroprusside, nitroglycerine etc.) hemoglobin conjugate and composition classified in class 514, subclass 6+; class 600/320+; class 424/193.1+ , class 530, subclass 350+ and various other subclasses dependent upon choice of NO donor.

VIII. Claim 50 drawn to a method for treating/preventing an NO mediated disorder by administering a heme based blood substitute and inhaled NO, classified in class 514, subclass 832 and class 423, subclasses 374 and 405.

IX. Claims 51 and 52 drawn to methods of delivering CO-derivatized hemoglobin, classified in class 514, subclass 6+.

X. Claims 53-55 drawn to an electron acceptor (e.g. NAD, FAD, superoxide dismutase etc.) nitrosylhemoglobin conjugate and composition classified in class 514, subclass 6+, 530, class 350+, class 435, subclass 183+, class 536, subclass 26.24+ and additional classes dependent upon the electron acceptor.

XI. Claims 56-58 drawn to a nitric oxide synthase hemoglobin conjugate and composition classified in class 514, subclass 6+, class 530, subclass 350+, class 435, subclass 183+.

XII. Claims 59-60 drawn to erythrocytes comprising nitrosylhemoglobin and a method of making thereof classified in class 424, subclasses 93.73, 529, 533 and class 514, subclass 6+.

XIII. Claim 61 drawn to a method for treating shock by administering hemoglobin alpha chains, classified in class 514, subclass 6+ and class 530, subclass 350+.

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XIV. Claim 62 drawn to a method for treating/preventing an NO-mediated disease by administering hemoglobin beta chains, classified in class 514, subclass 6+ and class 530, subclass 350+.

2. The methods of groups I, II, III, V, VIII, IX, XIII and XIV are patentably distinct methods since the methods have different modes of operation (e.g. different steps) and/or, different function and/or utilize different compounds in different methods which achieve totally different objectives .

3. The compounds and the methods of making thereof of Groups IV, VI, VII, X, XI and XII are patentably distinct, each from the other, compared to II and IV these groups contain different compounds or compositions containing compounds, which vary in chemical structure from one another and/or are capable of separate manufacture and/or use and/or possess different physicochemical properties.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification; the manual and computer searches required for the different Groups is different; and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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ELECTION OF SPECIES

5. The nitrosating agents of Group I; the NO donor of Group VII; and the electron acceptor of Group X; are all separately generic to a plurality of disclosed patentably distinct species comprising different structurally distinct compounds (e.g. for NO donors consider organic nitrates, S-nitroso-N-acetyl cysteine: see specification page 8; for Groups VII and X see the respective dependent claims relating therein).

Accordingly, upon selection of one of the Group I, VII or X inventions, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

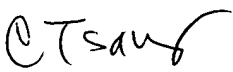
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (703) 308-0254.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 9, 1998



Bennett Celsa



CECILIA J. TSANG
SUPERVISORY PATENT EXAMINER
GROUP 1800